DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 10, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-01
Donald D. Elder, President
Reel Food Service, Inc.
304 Americana Boulevard
Boise, Idaho 83701

WARNING LETTER

Dear Mr. Elder:

We inspected your firm located at 304 Americana Boulevard, Boise, Idaho, on August 20, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you, some of which were previously brought to your attention, cause your cooked crabmeat and ready to eat products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for canned, vacuum sealed, refrigerated dungeness crabmeat to control the food safety hazards of pathogen survival and growth at receiving and refrigerated storage.

2. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for cooked ready-to-eat products that are received and distributed as refrigerated products (cooked Oregon shrimp meat, and whole cooked dungeness crab) to control the food safety hazards of pathogen survival and growth at receiving and refrigerated storage.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and

Cosmetic Act and all applicable regulations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact CO Elrand at (425) 483-4913, or email me at lelrand@ora.fda.gov.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: ISDH with disclosure statement